REMARKS

Claims 1, 4 – 12 and 15 – 20 are currently pending. Of these, Claims 1, 15, and 16 are independent. In the most recent Office Action, the Examiner rejected Claims 9 and 20 under Section 112, second paragraph as allegedly indefinite. The Examiner also rejected all pending claims under Section 103 as allegedly obvious over U.S. Patent No. 6,194,001 to Gribbon et al. ("Gribbon") combined with the Buckton et al. publication ("Buckton").

All rejections are respectfully traversed. Favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Indefiniteness Rejections.

The Examiner asserts the limitation "the active substance" in Claim 9 is indefinite because, in his view, it is not clear whether this refers to amoxicillin or clavulanic acid. The Examiner also contends this limitation lacks antecedent basis. In response, Applicants have amended Claim 9 to delete the "active substance" and to positively recite amoxicillin instead.

The Examiner also asserts the limitation "up to about 1500 mg of an active substance" in Claim 20 in indefinite. The Examiner contends that the two modifiers "up to" and "about" cannot be used in combination. While Applicants believe the subject terms make perfectly good sense when used together, they have nonetheless deleted the term "about" from Claim 20 in order to avoid quibbling over this issue and to advance prosecution on the merits. The claim still should be construed to call for "approximate" amounts, since exactitude in this regard is not a feature or requirement of the claimed invention.

In view of the foregoing, it is respectfully submitted that any possible indefiniteness in Claims 9 and 20 has been overcome. Accordingly, Applicants submit that the indefiniteness rejections should now be withdrawn.

II. The Prior Art Rejections.

The Examiner argues that Claims 1, 4 – 12 and 15 – 20 would have been obvious to a person of ordinary skill from a combination of the Gribbon patent with the Buckton publication. With all due respect, Applicants submit that this rejection is not well taken, and that the same should be withdrawn and the claims allowed.

Claims 1, 15, and 16 each call for, *inter alia*, a pharmaceutical tablet which comprises amoxicillin, clavulanic acid and silicified microcrystalline cellulose or "SMCC." The claims further require the absence of any disintegrant or superdisintegrant in the tablet other than the SMCC. In other words, SMCC is present as the sole disintegrant in the tablet. The purported combination of Gribbon with Buckton would not have suggested this formulation to a person of ordinary skill who had no knowledge of Applicants' invention.

The Examiner concedes that Gribbon does not mention use of SMCC at all, much less the use of SMCC alone as the only functioning disintegrant or superdisintegrant. Nonetheless, the Examiner argues that Gribbon does teach the use of "ordinary" microcrystalline cellulose or "MCC" as a disintegrant, and that it would have been obvious for a person of ordinary skill to substitute SMCC in place of MCC in the Gribbon formulation in view of what is taught in Buckton.

Again, Applicants submit this argument is unfounded. The present claims require use of SMCC as the only "disintegrant" or "superdisintegrant" in the composition. No person of ordinary skill would be led by Buckton and Gribbon to use SMCC as the sole disintegrant in a formulation as claimed by Applicants. This would not have been obvious to a person of skill in the art from Gribbon with Buckton.

A primary reason Applicants' claimed invention would not have been obvious from the cited art is that Buckton touts the alleged superiority of SMCC over SMC for use as a "compression aid" for pharmaceutical formulations. This is plainly not a teaching to substitute SMCC for SMC for any / all purposes, and it also clearly shows they are not simply "interchangeable" as asserted by the Examiner. In fact, Buckton's

teachings that SMCC is a superior compression aid vis-à-vis MCC would dissuade one of skill from even assuming interchangeability of the two materials for use as a "disintegrant."

A disintegrant is the antithesis of a compression aid. As described in the attached copy of published U.S. application 2006/0057218 at par. 39, a "compression aid" is known in the pharmaceutical industry as an excipient which helps in "plastic deformation when tableting." Based on this, an allegedly superior "compression acid" very clearly would not be thought to also be a superior "disintegrant," which, unlike a compression aid, would be a substance which promotes the separation of materials into particles such as in particlizer like a grinder or shredder or the like; and/or a substance which helps keep particles from coalescing or which hinders agglomeration of smaller particles into larger particles or masses, etc.

In view of the above, it should be evident that the Buckton paper would not have suggested to a person of skill that SMCC would be "obvious to try" in place of MCC for use as a disintegrant in a pharmaceutical formulation as claimed, much less a disintegrant that would be effective by itself.

It is also evident that Gribbon would lead a person of skill away from using MCC as the only disintegrant. Rather, Gribbon teaches one to use a combination of disintegrants. In particular, Gribbon teaches that MCC is preferably combined with sodium starch glycolate, crosccarmellose sodium or CLPVP at column 2, lines 65 – 67. Of particular note is the fact that not one of Gribbon's examples discloses a dispersible tablet said to comprise MCC as the only disintegrant. In fact, none of Gribbon's examples discloses a dispersible tablet comprising any single disintegrant used by itself. Instead, each of Gribbon's examples discloses a dispersible tablet containing at least three different distintegrants in the tablet composition.

Thus, one of ordinary skill following the teachings of Gribbon would undoubtedly have been led to use multiple disintegrants in combination with one another. Nothing in

the purported combination of references suggests or hints at the use of SMCC as the only disintegrant in a formulation according to Applicants' claims.

Buckton might be said to suggest substituting SMCC for MCC for use as a "compression aid" in tableting a pharmaceutical formulation, but this most certainly would have not suggested the same substitution in the case of a disintegrant. At a minimum, Buckton teaches that SMCC and MCC have materially different properties, and its suggestion that SMCC would work better than MCC as a "compression aid" would plainly not have suggested that SMCC could also be substituted for MCC as a disintegrant, which is essentially the opposite functionality from that of a disintegrant. This, combined with the clear preference in Gribbon for the use of multiple disintegrants, cannot reasonably be said to suggest Applicants' pharmaceutical formulation as claimed which uses SMCC as the only disintegrant.

Accordingly, while there has been no showing as to why a person of skill would reasonably have combined Gribbon and Buckton vis-à-vis use of disintegrants, the fact remains that Gribbon, considered in combination with Buckton, simply would not have lead a person of ordinary skill to make a pharmaceutical product as claimed containing SMCC as the only disintegrant.

It is to be noted that when a reference is cited in an obviousness rejection, the reference must be taken as a whole for all that it teaches. *See In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (C.C.P.A. 1965) ("it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.") In other words favorable teachings or suggestions in the reference may not be utilized while ignoring unfavorable portions of the reference. In particular, Gribbon's clear teachings to use a combination of distintegrants and not just MCC alone, cannot be ignored.

Thus, Applicants submit that independent Claims 1, 15, and 16 patentably distinguish over Gribbon and Buckton, whether considered alone or in combination.

Moreover, since the dependent claims include all of the limitations of the independent claims, they also patentably distinguish over the cited references for at least the same reasons.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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